IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

MERCK SHARP & DOHME B.V. and ORGANON USA INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN INC. and MYLAN API US LLC,

Defendants.

1:20-CV-61 (Kleeh)
C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Sharp & Dohme B.V. ("Merck B.V.") and Organon USA Inc. ("Organon") (together, "Merck"), by their attorneys, bring this complaint against Defendants Mylan Pharmaceuticals Inc. ("MPI"), Mylan Inc. ("Mylan Inc."), and Mylan API US LLC ("Mylan API") (collectively, "Mylan Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., including 35 U.S.C. § 271(e)(2), the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Mylan Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import all strengths of a purported generic version of Bridion® (sugammadex) Injection prior to the expiration of U.S. Patent No. RE44,733 ("the '733 patent").

PARTIES

2. Plaintiff Merck Sharp & Dohme B.V. ("Merck B.V.") is a corporation organized and existing under the laws of the Netherlands with its principal place of business at Waarderweg 39, Haarlem, Netherlands 2031 BN. Merck B.V. is an indirect, wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation, which has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

3. Plaintiff Organon USA Inc. ("Organon") is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Organon is a wholly owned subsidiary of Merck & Co., Inc.

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("MPI") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, MPI is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

5. On information and belief, Defendant Mylan Inc. ("Mylan Inc.") is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Robert J. Coury Center, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market, through various operating subsidiaries, including MPI and Mylan API.

6. On information and belief, Defendant Mylan API US LLC ("Mylan API") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 45 Napoleon Court, Somerset, New Jersey 08873. On information and belief, Mylan API is in the business of, among other things, manufacturing, promoting, marketing, selling, offering for sale, using, distributing, and importing into the United States, generic versions of branded pharmaceutical drugs for the U.S. market.

7. On information and belief, MPI and Mylan API are wholly owned subsidiaries of Mylan Inc.

8. In July 2019, Mylan N.V., the Mylan Defendants' parent company, announced a definitive agreement to combine Mylan N.V. with Upjohn Inc. ("Upjohn"), Pfizer

Inc.'s off-patent branded and generic established medicines business, creating a new global pharmaceutical company. Upon information and belief, the deal is expected to close in mid-2020.

9. By a letter dated February 18, 2020 ("Mylan Notice Letter"), MPI notified Merck that MPI had submitted to the FDA ANDA No. 213915 ("Mylan's ANDA") for purported generic versions of sugammadex injection, 200 mg/2 mL and 500 mg/5 mL ("Mylan ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products in or into the United States, including West Virginia, prior to the expiration of the '733 patent.

10. On information and belief, MPI, Mylan Inc., and Mylan API acted in concert to prepare and submit Mylan's ANDA and the Mylan Notice Letter. On information and belief, Mylan API holds Drug Master File No. 32311 for sugammadex sodium. On information and belief, Mylan API assisted in the preparation of and submission of Mylan API's DMF to the FDA. On information and belief, the purpose of Mylan API's Drug Master File includes clinical trial supply and the ultimate supply that will be used in manufacturing the Mylan ANDA Products if Mylan's ANDA, submitted to the FDA by MPI, is approved.

11. On information and belief, MPI, Mylan Inc., and Mylan API know and intend that upon approval of Mylan's ANDA, MPI, Mylan Inc., and/or Mylan API will manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Mylan ANDA Products throughout the United States, including in West Virginia. On information and belief, MPI, Mylan API, and Mylan Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to the Mylan ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, MPI, Mylan Inc., and Mylan API participated, assisted, and cooperated in carrying out the acts complained of herein.

12. On information and belief, following any FDA approval of Mylan's ANDA, MPI, Mylan Inc., and Mylan API will act in concert to manufacture, promote, market, sell, offer for sale, import, use, and/or distribute the Mylan ANDA Products throughout the United States, including West Virginia.

JURISDICTION AND VENUE

13. Merck incorporates each of the preceding paragraphs 1–12 as if fully set forth herein.

14. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271, for infringement of the asserted patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over MPI because MPI is a corporation organized and existing under the laws of West Virginia and because MPI has its principal place of business in West Virginia.

16. MPI is also subject to personal jurisdiction in West Virginia because, among other things, MPI has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being sued in this Court. On information and belief, MPI develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia.

17. On information and belief, MPI is registered as a "Manufacturer" with the State of West Virginia's Board of Pharmacy under License Nos. MR0000064, MR0551059, and as a "Wholesale Distributor" under License No. WD0559319. On information and belief, MPI

will use this license to offer for sale and to sell the Mylan ANDA Products throughout the United States, including in West Virginia.

18. On information and belief, MPI is registered with the West Virginia Secretary of State as a business operating in the State of West Virginia under Organization No. 20402.

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1400(b) as to MPI because, on information and belief, MPI has a regular and established place of business in West Virginia, and because, on information and belief, MPI has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Merck by preparing or assisting in preparing Mylan's ANDA in West Virginia and/or with the intention of seeking to market the Mylan ANDA Products nationwide, including within West Virginia.

20. Mylan Inc. is subject to personal jurisdiction in West Virginia because, among other things, Mylan Inc. itself, and through its wholly owned subsidiaries MPI and Mylan API, purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Mylan Inc. itself, and through its wholly owned subsidiaries MPI and Mylan API, develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, on information and belief, it controls and dominates MPI and Mylan API, and therefore the activities of MPI and Mylan API in this jurisdiction are attributed

to Mylan Inc. Moreover, Mylan Inc., through its wholly owned subsidiary MPI, has a regular and established place of business in West Virginia.

21. On information and belief, Mylan Inc. is registered with the West Virginia Secretary of State as a business operating in the State of West Virginia under Organization No. 230499. On information and belief, Mylan Inc. will use this license to offer for sale and to sell the Mylan ANDA Products throughout the United States, including in West Virginia.

22. Mylan API is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being sued in this Court. On information and belief, Mylan API develops, manufactures, imports, markets, distributes, uses, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia, and therefore transacts business within the State of West Virginia related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. Additionally, this Court has personal jurisdiction over Mylan API because on information and belief Mylan API assisted in the preparation and submission of Drug Master File No. 32311 to the FDA.

23. On information and belief, Mylan API is registered as a "Manufacturer" with the State of West Virginia's Board of Pharmacy under License No. MR0551682. On information and belief, Mylan API, itself and through its affiliates, will use this license to offer for sale and to sell the Mylan ANDA Products throughout the United States, including in West Virginia.

24. MPI, in concert with Mylan Inc. and Mylan API, has committed an act of infringement in this judicial district by filing ANDA No. 213915 with the intent to make, use, sell,

offer for sale, and/or import the Mylan ANDA Products in or into this judicial district, prior to the expiration of the '733 patent.

25. Upon information and belief, MPI, Mylan Inc., and Mylan API hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products in the United States. The Mylan.com website states that "[i]n the U.S., the world's largest pharmaceutical market, Mylan products fill one out of every 14 prescriptions dispensed." *See* Mylan.com, Business Segments tab, *available at* https://www.mylan.com/en/about-mylan/business-segments (last visited March 18, 2020). The Mylan.com website also states that "[i]n the U.S., we have one of the largest product portfolios among all generic pharmaceutical companies." *Id.* The Mylan.com website does not distinguish the Mylan Defendants or provide separate websites for the Mylan Defendants. *See id.* The Mylan.com website refers to Mylan Defendants' corporate affiliates, agents and subsidiaries as "Mylan" and "we". *See id.* The Securities and Exchange Commission Form 10-K available on the Mylan.com website includes the activites of MPI and Mylan Inc., including the revenue earned. *See* Mylan N.V. 2019 United States Securities and Exchange Comission Form 10K, *available at* https://investor.mylan.com/node/28936/html (last visited March 26, 2020).

26. On information and belief, a corporate website operated by and for the benefit of the Mylan Defendants and their corporate affiliates, publicly touts the Mylan Defendants' West Virginia presence. *See* mylanbetterhealth.com, The Mylan Story tab, *available at*, https://mylanbetterhealth.com/en/us/west-virginia (last visited March 19, 2020). This website states that in "2018, Mylan generics saved West Virginia ~ $150 million."

27. Mylan Defendants have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Mylan ANDA

Products, that will be purposefully directed at West Virginia and elsewhere in the United States.

28. On information and belief, Mylan Defendants have systematic and continuous contacts with West Virginia; have established distribution channels for drug products in West Virginia; regularly and continuously conduct business in West Virginia, including by selling drug products in West Virginia, either directly or indirectly through their subsidiaries, agents, or affiliates; have purposefully availed themselves of the privilege of doing business in West Virginia; have a regular and established place of business in West Virginia; and derive substantial revenue from the sale of drug products in West Virginia.

29. On information and belief, if Mylan's ANDA is approved, Mylan Defendants will manufacture, market, promote, sell, offer for sale, import, use and/or distribute the Mylan ANDA Products within the United States, including in West Virginia, consistent with Mylan Defendants' practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Mylan Defendants regularly do business in West Virginia, and their practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in West Virginia. On information and belief, Mylan Defendants' generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia. On information and belief, the Mylan ANDA Products will be prescribed by physicians practicing in West Virginia, dispensed by pharmacies located within West Virginia, and used by patients in West Virginia. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of the '733 patent in the event that the Mylan ANDA Products are approved before the '733 patent expires.

30. On information and belief, Mylan Defendants derive substantial revenue

from generic pharmaceutical products that are used and/or consumed within West Virginia, and that are manufactured by Mylan Defendants and/or for which MPI, Mylan Inc., and/or Mylan API is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which MPI and/or Mylan Inc. and/or Mylan API is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in West Virginia.

31. On information and belief, MPI has consented to jurisdiction in West Virginia in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *Almirall, LLC v. Mylan Pharm. Inc.*, No. 1:20-cv-00006-IMK (N.D. W. Va. Feb. 3, 2020); *AstraZeneca AB v. Mylan Pharm. Inc.*, Nos. 1:18-cv-00193-IMK, 1:19-cv-00203-IMK (N.D. W. Va. Nov. 15, 2019); *Pfizer Inc. v. Mylan Pharm. Inc.*, No. 1:19-cv-00097 (IMK) (N.D. W. Va. July 10, 2019).

32. On information and belief, Mylan Inc. has consented to jurisdiction in West Virginia in one or more prior cases arising out of the filing of its ANDAs, and/or has filed counterclaims in such cases. *See, e.g.*, *Anacor Pharm., Inc. v. Mylan Pharm. Inc.*, No. 1:18-cv-00202-IMK (N.D. W. Va. Dec. 14, 2018); *Sanofi-Aventis U.S. LLC v. Mylan N.V.*, No. 1:17-cv-00181-IMK (N.D. W. Va. Nov. 21, 2017); *Sanofi-Aventis U.S. LLC v. Mylan Pharm. Inc.*, No. 1:17-cv-00005-IMK (N.D. W. Va. May 9, 2017).

33. On information and belief, venue is proper in this Court under 28 U.S.C. §§ 1391(c) and (d) and/or 1400(b).

THE PATENT-IN-SUIT

34. Merck B.V. is the owner and assignee of the ’733 patent, entitled “6-Mercapto-Cyclodextrin Derivatives: Reversal Agents For Drug-Induced Neuromuscular Block” (attached as Exhibit A). Merck B.V. has the right to enforce the ’733 patent.

35. The ’733 patent was duly and legally issued on January 28, 2014. The ’733

patent was a reissue of U.S. Patent No. 6,670,340, which was duly and legally issued on December 30, 2003.

36. The ’733 patent includes claims that recite 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, compositions containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, methods of using 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin, and kits containing 6-per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin.

37. 6-Per-deoxy-6-per-(2-carboxyethyl)thio-γ-cyclodextrin is also referred to as sugammadex.

38. The FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) currently lists the expiration of the ’733 patent as January 27, 2021. On February 4, 2020, the United States Patent and Trademark Office (“PTO”) issued a Notice Of Final Determination on the patent term extension (“PTE”) application for the ’733 patent, wherein the PTO determined that the ’733 patent is eligible for 5 years of PTE (attached as Exhibit B). Therefore, after the PTE certificate is issued, the expiration of the ’733 patent will be January 27, 2026.

THE BRIDION® DRUG PRODUCT

39. Organon is the holder of New Drug Application (“NDA”) No. 022225, under which the FDA approved the commercial marketing of Bridion® (sugammadex) Injection (“Bridion®”) on December 15, 2015, under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 355(a). Bridion® is approved for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery. Bridion® is distributed in the United States by Merck Sharp and Dohme Corp., a wholly owned subsidiary of Merck & Co., Inc., in 200 mg/2 mL and 500 mg/5 mL strengths in a single-dose vial for bolus injection. A true and correct copy of the current prescribing

information for Bridion® is attached as Exhibit C.

40. Bridion® is a first-in-class drug that works differently than prior agents used for the reversal of neuromuscular blockade. The active ingredient in Bridion®, sugammadex, is a modified cyclodextrin that acts by directly encapsulating, binding, and inactivating agents used by healthcare providers to induce neuromuscular blockade in patients undergoing surgery, e.g., rocuronium or vecuronium, to reverse their effects. After intravenous injection, Bridion® distributes through plasma and binds to such neuromuscular blocking agents ("NMBAs") to form a complex. This process reduces the amount of NMBA available to bind to nicotinic cholinergic receptors in the neuromuscular junction, resulting in the reversal of neuromuscular blockade.

41. By this mechanism, Bridion® also avoids several of the side effects associated with prior reversal agents, such as acetylcholinesterase inhibitors. Traditional reversal agents are co-administered with other agents to manage these side effects, but the co-administered agents can cause a number of additional side effects. Moreover, Bridion® is capable of reversing the complete and prolonged block of neuromuscular function (known as "profound block") that can occur with the administration of NMBAs. Further, intravenous administration of sugammadex results in more rapid recovery from moderate or deep neuromuscular blockade in patients undergoing surgery who received rocuronium or vecuronium, as compared to neostigmine or succinylcholine. Because of at least these unique features, Bridion® has been viewed as a significant advance in the field of anesthesiology.

42. Bridion®, as well as methods of using Bridion®, are covered by one or more claims of the '733 patent. The '733 patent has been listed in connection with NDA No. 022225 in the FDA's Orange Book.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

43. On information and belief, Mylan Defendants have submitted or caused the

submission of Mylan's ANDA to the FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Mylan ANDA Products, as a purported generic version of Bridion®, prior to the expiration of the '733 patent.

44. On information and belief, the FDA has not yet approved Mylan's ANDA.

45. In the Mylan Notice Letter, MPI notified Merck of the submission of Mylan's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Products prior to the expiration of the '733 patent.

46. In the Mylan Notice Letter, MPI acknowledged that the Reference Listed Drug for Mylan's ANDA is Bridion®. Bridion® is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery.

47. In the Mylan Notice Letter, MPI also notified Merck that, as part of its ANDA, MPI had filed a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '733 patent.

48. On information and belief, MPI submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '733 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Products.

49. In the Mylan Notice Letter, MPI stated that the Mylan ANDA Products contain sugammadex as an active ingredient. On information and belief, Mylan Defendants' submission of Mylan's ANDA was based upon the use of Mylan API's Drug Master File.

50. On information and belief, Mylan Defendants, through their own actions

and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Mylan's ANDA, and intend to further prosecute Mylan's ANDA. On information and belief, if the FDA approves Mylan's ANDA, Mylan Defendants will manufacture, distribute, promote, market, offer for sale, or sell the Mylan ANDA Products within the United States, or will import the Mylan ANDA Products into the United States. On information and belief, if the FDA approves Mylan's ANDA, Mylan Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Mylan ANDA Products in or into the United States.

51. Merck brings this action within forty-five days of receipt of the Mylan Notice Letter. Accordingly, Merck is entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I – INFRINGEMENT OF THE '733 PATENT

52. Merck incorporates each of the preceding paragraphs 1–51 as if fully set forth herein.

53. The Mylan ANDA Products, and the use of the Mylan ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent, because claim 1 of the '733 patent encompasses the sugammadex utilized in the Mylan ANDA Products.

54. In the Mylan Notice Letter, MPI did not contest infringement of claims 1-5 and 11-14 of the '733 patent.

55. Mylan Defendants' submission of Mylan's ANDA with a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Products in or into the United States before the expiration of the '733 patent is an act of infringement of the '733 patent under 35 U.S.C.

§ 271(e)(2)(A).

56. If approved by the FDA, Mylan Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Mylan ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(a)-(c).

57. On information and belief, Mylan Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mylan ANDA Products in or into the United States immediately and imminently upon approval of Mylan's ANDA.

58. The commercial manufacture, use, sale, offer for sale, or importation of the Mylan ANDA Products in or into the United States would infringe one or more claims of the '733 patent.

59. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation of the Mylan ANDA Products in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '733 patent.

60. On information and belief, upon FDA approval of Mylan's ANDA, Mylan Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Mylan ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Mylan Defendants will knowingly and intentionally accompany the Mylan ANDA Products with a product label or product insert that will include instructions for using or administering the Mylan ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent.

Accordingly, Mylan Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Mylan ANDA Products to directly infringe the '733 patent. On information and belief, Mylan Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Mylan Defendants are encouraging infringement.

61. On information and belief, Mylan Defendants plan and intend to, and will, actively induce infringement of the '733 patent when Mylan's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Mylan Defendants' activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

62. On information and belief, Mylan Defendants know that the Mylan ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the Mylan ANDA Products are not a staple article or commodity of commerce, and that the Mylan ANDA Products and accompanying proposed labeling are not suitable for substantial noninfringing use. On information and belief, Mylan Defendants plan and intend to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Mylan's ANDA.

63. Notwithstanding Mylan Defendants' knowledge of the claims of the '733 patent, Mylan Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the Mylan ANDA Products with its product labeling in or into the United States following FDA approval of Mylan's ANDA prior to the expiration of the '733 patent.

64. The foregoing actions by Mylan Defendants constitute and/or will constitute direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and contribution to the infringement by others of the '733 patent.

65. On information and belief, MPI, in concert with its agents, affiliates, and subsidiaries, including Mylan Inc. and Mylan API, filed Mylan's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '733 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mylan ANDA Products. On information and belief, Mylan Defendants have acted with full knowledge of the '733 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by Mylan Defendants of the '733 patent was and is willful. Mylan Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

66. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Mylan Defendants are enjoined from directly infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Mylan Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

COUNT II – DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '733 PATENT

67. Merck incorporates each of the preceding paragraphs 1–66 as if fully set forth herein.

68. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

69. There is an actual case or controversy such that the Court may entertain

Merck's request for declatory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

70. The Mylan ANDA Products, and the use of the Mylan ANDA Products, are covered by one or more claims of the '733 patent, including at least claim 1 of the '733 patent, because claim 1 of the '733 patent encompasses the sugammadex utilized in the Mylan ANDA Products.

71. In the Mylan Notice Letter, MPI did not contest infringement of claims 1-5 and 11-14 of the '733 patent.

72. The Mylan Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's ANDA Products before the expiration date of the '733 patent, including Mylan's filing of ANDA.

73. If approved by the FDA, Mylan Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of the Mylan ANDA Products in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(a)-(c).

74. On information and belief, Mylan Defendants will engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Mylan ANDA Products in or into the United States immediately and imminently upon approval of Mylan's ANDA.

75. The commercial manufacture, use, sale, offer for sale, or importation of the Mylan ANDA Products in or into the United States will infringe one or more claims of the '733 patent.

76. On information and belief, the commercial manufacture, use, sale, offer for

sale, or importation of the Mylan ANDA Products in accordance with, and as directed by, its proposed product labeling will infringe one or more claims of the '733 patent.

77. On information and belief, upon FDA approval of Mylan's ANDA, Mylan Defendants will, through their own actions or through the actions of their agents, affiliates, and subsidiaries, market and/or distribute the Mylan ANDA Products to resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users. On information and belief, Mylan Defendants will knowingly and intentionally accompany the Mylan ANDA Products with a product label or product insert that will include instructions for using or administering the Mylan ANDA Products, which are substantially similar to the instructions in the prescribing information for Bridion®, attached as Exhibit C, and which, if followed, will infringe the '733 patent. Accordingly, Mylan Defendants will induce resellers, pharmacies, hospitals, clinics, healthcare professionals, and other end users of the Mylan ANDA Products to directly infringe the '733 patent. On information and belief, Mylan Defendants will encourage acts of direct infringement with knowledge of the '733 patent and knowledge that Mylan Defendants are encouraging infringement.

78. On information and belief, Mylan Defendants plan and intend to, and will, actively induce infringement of the '733 patent when Mylan's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval. Mylan Defendants' activities will be done with knowledge of the '733 patent and specific intent to infringe that patent.

79. On information and belief, Mylan Defendants know that the Mylan ANDA Products and proposed labeling are especially made or adapted for use in infringing the '733 patent, that the Mylan ANDA Products are not a staple article or commodity of commerce, and that the Mylan ANDA Products and accompanying proposed labeling are not suitable for substantial

noninfringing use. On information and belief, Mylan Defendants plan and intend to, and will, contribute to infringement of the '733 patent immediately and imminently upon approval of Mylan's ANDA.

80. Notwithstanding Mylan Defendants' knowledge of the claims of the '733 patent, Mylan Defendants have continued to assert their intent to manufacture, use, offer for sale, sell, distribute, and/or import the Mylan ANDA Products with its product labeling in or into the United States following FDA approval of Mylan's ANDA prior to the expiration of the '733 patent.

81. The foregoing actions by Mylan Defendants will constitute direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and contribution to the infringement by others of the '733 patent.

82. On information and belief, MPI, in concert with its agents, affiliates, and subsidiaries, including Mylan Inc. and Mylan API, filed Mylan's ANDA with a Paragraph IV Certification without adequate justification for asserting that the '733 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation in or into the United States of the Mylan ANDA Products. On information and belief, Mylan Defendants have acted with full knowledge of the '733 patent and without a reasonable basis for believing that they would not be liable for direct infringement of the '733 patent; active inducement of infringement by others of the '733 patent; and/or contribution to the infringement by others of the '733 patent. On information and belief, the direct and indirect infringement by Mylan Defendants of the '733 patent was and is willful. Mylan Defendants' conduct renders this case "exceptional" under 35 U.S.C. § 285.

83. Merck will be substantially and irreparably damaged by infringement of the '733 patent. Unless Mylan Defendants are enjoined from directly infringing the '733 patent,

actively inducing infringement of the '733 patent, and contributing to the infringement of the '733 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law, and considering the balance of hardships between Merck and Mylan Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of an injunction.

84. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Mylan ANDA Products will constitute infringement of one or more claims of the '733 patent.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the '733 patent has been infringed under 35 U.S.C. § 271(e)(2) by Mylan Defendants' submission to the FDA of Mylan's ANDA;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of the Mylan ANDA Products, or any other drug product that infringes or the use of which infringes the '733 patent, be not earlier than the expiration date of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Mylan Defendants, and all persons acting in concert with Mylan Defendants, from the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mylan ANDA Products, or any other drug product covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mylan ANDA Products, or any

other drug product that is covered by or whose use is covered by the '733 patent, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity, will infringe, induce the infringement of, and contribute to the infringement by others of the '733 patent;

(e) A declaration that Mylan Defendants' commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the Mylan ANDA Products, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '733 Patent by Mylan Defendants under one or more of 35 U.S.C. § 271(a), (b), and (c);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Mylan Defendants engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States of the Mylan ANDA Products, or any product that infringes the '733 patent, or induces or contributes to such conduct, prior to the expiration of the '733 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A judgment that Mylan Defendants willfully and deliberately infringed the '733 patent;

(h) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: April 1, 2020

Respectfully submitted,

/s/ Carrie Goodwin Fenwick
Carrie Goodwin Fenwick (WV Bar 7164)

Shanna L. Brown (WV Bar 12516)
GOODWIN & GOODWIN, LLP
300 Summers Street
Suite 1500
Charleston, WV 25301
Tel: (304) 346-7000
Fax: (304) 344-9692
cgf@goodwingoodwin.com
slb2@goodwingoodwin.com

Attorneys for Plaintiff
Merck Sharp & Dohme B.V.
and Organon USA Inc.